K130690

SPECIAL 510(K) SUMMARY

JUN 12 2013

Submitted By:
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Date Originated: March 12th, 2013
Trade Name: Z-800 Infusion System
Models: Z-800, Z-800W, Z-800F, Z-800WF
Common Name: Volumetric Infusion Pump
Classification Name: Infusion Pump
Product code: FRN 880.5725

Establishment Registration Number: 3006575795

Predicate Devices
Z-800 Infusion System (K100705)

Intended Use

The Z-800 Infusion system is intended to provide intravenous infusion of parenteral fluids, blood and blood products to a patient under the direction or supervision of physician or other certified health care professional.

The intended use of the modified device is the same as the predicate device.

Device Description and Comparison:

The Z-800 Infusion system is intended to provide intravenous infusion of parenteral fluids, blood and blood products to a patient under the direction or supervision of physician or other certified health care professional.

The Z-800 Infusion System consists of the infusion pumps and approved external IV administration sets.

Zyno Medical LLC is submitting this **Special 510(k): Device Modification** to request a modification for the approved infusion system. The major modifications are as following:

1. Added a counter in software for cumulative volume of fluid infused in order to monitor pump utilization. The odometer feature enables pump display a reminder for user to service the pump once a preset volume limit is reached.
2. Implemented optional set based free flow protection. Modified set based free flow protection mechanism consists of a proprietary pinch clamp on the standard IV set tubing and an optional spring loaded clamp holder module on the pump. The pinch clamp can be manually opened for priming. The clamp holder is designed such that the pinch clamp is automatically closed once it is loaded into the clamp holder. Upon pump door close, the pump door activates the pinch clamp loaded in the clamp holder to open to allow flow go through. Upon pump door open, the spring in the clamp holder forces the pinch clamp to close. When the IV set is removed from the pump, the pinch clamp remains at closed position to avoid unintended free flow. A sensor on the clamp holder detects presence of the pinch clamp. "No Clamp" status can be displayed on pump screen to inform user that the clamp is absent.
3. Implemented optional Wi-Fi communication module for serial port to enable bidirectional communication through RF signal. A self-contained serial Wi-Fi convertor module is embedded into the Z-800 infusion pump to enable wireless communication. The Z-800 infusion pump sends serial command to the Wi-Fi convertor module. The Wi- Fi convertor module translates the serial communication command from the Z-800 infusion pump to RF signals and responsible for handling communication protocol with external devices. The serial Wi-Fi convertor enables the user to initiate a query on the pump for external information by entering partial patient identifier information as search criteria. External information returned from the query may include patient information, such as name, date of birth, and IV medication order. The patient and order information are presented to the healthcare professional during infusion programming process to be confirmed for association with the infusion. The Wi-Fi convertor also enables Z-800 infusion pump to publish infusion status data, with the associated patient and order identifiers, which can be utilized by external systems such as EMR.
4. Added an ESD/EMI shielding cap for serial port to enhance pump survivability under injection of Electromagnetic noise and Electrostatic Discharge.

5. Optimized pressure sensor zero point value determination process for better accuracy.
6. Optimized peristaltic plate to maximize durability of peristaltic module.
7. Optimized peristaltic cams in peristaltic module to maximize its durability.
8. Optimized rubber feet for increased durability.

All engineering changes since the last 510K (K100705) approval have been listed above. We believe these modifications are eligible for the Special 510 (k) process since they have the same fundamental scientific technology and intended use as the predicate device. The principles of operation, method of manufacturing, and the application remain the same.

The equivalency matrix (Table 1) compares the modified infusion system with the predicate device (K100705).

Table 1: Equivalency Matrix

Parameter	**Z-800 Infusion System (with Odometer)**	**Z-800 Infusion System (K100705)**
Pump Type	Volumetric Infusion Pump	Volumetric Infusion Pump
Intended use	The Z-800 Infusion system is intended to provide intravenous infusion of parenteral fluids, blood and blood products to a patient under the direction or supervision of physician or other certified health care professional.	The Z-800 Infusion system is intended to provide intravenous infusion of parenteral fluids, blood and blood products to a patient under the direction or supervision of physician or other certified health care professional.
Flow Rate Accuracy	±5%	±5%
Pumping mechanism	Linear peristaltic pump	Linear peristaltic pump
Free Flow Protection	Yes	Yes
Power source	AC: 100-250V 50-60 Hz DC: Internal Nickel Metal Hydride	AC: 100-250V 50-60 Hz DC: Internal Nickel Metal Hydride
Battery Life	8 hours at 125 ml/hr	8 hours at 125 ml/hr
Display	Program controlled dot matrix LCD	Program controlled dot matrix LCD

Parameter	Z-800 Infusion System (with Odometer)	Z-800 Infusion System (K100705)
Serial Communications	Bidirectional	Bidirectional
Case construction	Milled Aluminum & Sheet Metal Enclosure	Milled Aluminum & Sheet Metal Enclosure
Occlusion Pressure Setting	14 Level Adjustable	14 Level Adjustable
Warnings / Status	Low Battery Near End Infusion Complete Pump unattended KVO No Clamp (available when equipped with optional clamp holder) Service Due Soon Service Due	Low Battery Near End Infusion Complete Pump unattended KVO
Alarms	Occlusion Battery Empty Air-In-Line Door Open System Error No Drip (with optional drip sensor) Drip sensor connection (with optional drip sensor)	Occlusion Battery Empty Air-In-Line Door Open System Error No Drip (with optional drip sensor) Drip sensor connection (with optional drip sensor)
Operation Modes	Continuous Mode (Primary & Secondary) 10 Steps Sequence TPN Intermittent Blood Infusion User Saved Protocols	Continuous Mode (Primary & Secondary) 10 Steps Sequence TPN Intermittent Blood Infusion User Saved Protocols

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 12, 2013

Mei Zhang, PhD
President/ Chief Executive Officer
Zyno Medical LLC
10 Tech Circle
NATICK MA 01760

Re: K130690
Trade/Device Name: Z-800 Series Volumetric Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: May 15, 2013
Received: May 21, 2013

Dear Dr. Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA Mary S. Runner -S

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Acting Division Director
Division of Anesthesiology, General Hospital,
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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130690

Device Name: Z-800 Series Volumetric Infusion System

Indications for Use: The Z-800 Infusion system is intended to provide intravenous infusion of parenteral fluids, blood and blood products to a patient under the direction or supervision of physician or other certified health care professional.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K130690